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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/790,715	03/03/2004	Gregory M. Glenn	056707-5001-01	4303
9629	7590	07/20/2006	EXAMINER	
MORGAN LEWIS & BOCKIUS LLP 1111 PENNSYLVANIA AVENUE NW WASHINGTON, DC 20004			KIM, YUNSOO	
			ART UNIT	PAPER NUMBER
			1644	
DATE MAILED: 07/20/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

<p align="center"><b>Advisory Action</b> <b>Before the Filing of an Appeal Brief</b></p>	Application No. 10/790,715	Applicant(s) GLENN ET AL.	
	Examiner Yunsoo Kim	Art Unit 1644	

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 19 June 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.  
 b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

#### AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
 (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);  
 (b) ☐ They raise the issue of new matter (see NOTE below);  
 (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
 (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
 5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.  
 6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
 7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
 The status of the claim(s) is (or will be) as follows:  
 Claim(s) allowed: none.  
 Claim(s) objected to: none.  
 Claim(s) rejected: 106-159 and 161.  
 Claim(s) withdrawn from consideration: none.

#### AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
 9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
 10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

#### REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
See Continuation Sheet.  
 12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). \_\_\_\_\_.  
 13. ☐ Other: \_\_\_\_\_.

Continuation of 11. does NOT place the application in condition for allowance because:

claims 142-159 and 161 stand rejected under 35 USC 112, 1st paragraph for the reasons set forth in the office action mailed 4/24/06. Applicants' response filed 6/19/06 has been fully considered but they were not persuasive.

Applicants traversed the rejection based on that the method of inducing an immune response comprising a parenteral administration and a transdermal administration is enabled.

However, as acknowledged by the Applicants' response, Example 12 teaches intramuscular injection to the thigh and then the transcutaneous administration to the back of mice. The antigenic stimulations at an application site results the lymph collected is filtered through a set of defined lymph nodes of the local area. Distal and multiple applications of antigens to cervical and abdomen areas would not result one draining lymph nodes (Kuby, 2000, Immunology, 4<sup>th</sup> Ed. p. 47-53, of record).

Claims 106, 107, 109, 110, 114-121, 124, 125, 127, 128, 130 and 132-139 stand rejected under 35 U.S.C. 102(b) as being anticipated by WO 95/17211 (IDS reference, of record) as is evidenced by the Skills Checklist for immunization for the reasons set forth in the office action mailed 4/24/06.

Applicants' arguments filed on 6/19/06 have been fully considered but they are not persuasive.

Applicants traversed the rejection based on that the reference does not teach inducing immune response by applying to the skin and mucosal administration is not enabled.

Contrary to Applicant's argument that the reference teaching is limited to mucosal delivery of antigen and adjuvant, the '211 publication teaches applying the immunogenic composition such as vaccine comprising an antigen and adjuvant composition transdermally (p. 12, lines 12-13) as well as conventional administrations. In addition, the checklist was not supplied to disclose the pretreatment before the transcutaneous delivery. Rather, it was supplied that it is well known in the art to pretreat the skin prior to any immunization procedures.

Claims 106 - 108, 113, 122-126, 131, 140 and 141 stand rejected under 35 U.S.C. 103 as being unpatentable over WO 95/17211 (IDS reference, of record) as is evidenced by Skill Checklist for immunization, in view of U.S. Pat. No. 4, 810,499 (IDS reference, of record) for the reasons set forth in the office action mailed 4/24/06.

Applicants' arguments filed on 6/19/06 have been fully considered but they are not persuasive.

Applicants traversed the rejection based on that the deficiency of the '211 publication thus the combination is not obvious.

In light of the discussion of the '211 publication teaches transdermal and pretreatment to hydrate before immunization being well known and inherent process of immunization, the combination of the reference teachings remain obvious.


Claims 106, 111, 112, 124, 129 and 139 are rejected under 35 U.S.C. 103 as being unpatentable over WO 95/17211 (IDS reference, of record) as is evidenced by the Skill checklist for immunization, in view of U.S. Pat. No. 5,814,599 (IDS reference, of record) for the reasons set forth in the office mailed 4/24/06.

Applicants' arguments filed on 6/19/06 have been fully considered but they are not persuasive.

Applicants traversed the rejection based on that the deficiency of the '211 publication thus the combination is not obvious.

In light of the discussion of the '211 publication teaches transdermal and pretreatment to hydrate before immunization being well known and inherent process of immunization, the combination of the reference teachings remain obvious.

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July 17, 2006

  
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